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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,522	09/14/2004	Hidetoshi Hamamoto	2004-1425A	1134

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
WEBB, WALTER E	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,522	HAMAMOTO ET AL.	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☒ Claim(s) *8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/07/2007, 9/14/2006, 9/14/2004.

DETAILED ACTION

Claim Objections

Claims 8 and 9 are objected to because of the following informalities: the phrase "of from" does not provide a proper basis for the claimed percentage values. The claims should recite "in an amount of from." Appropriate correction is required.

Claim Rejections - 35 USC § 112

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, Applicant discloses a preparation "wherein the bactericidal agent is iodine-based bactericidal agent."

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

See. E.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "iodine-based" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See *Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid form others having the same activity or function. A description of what a material does, rather that of what it is, usually does not suffice. . . . The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of a genus, which features constitute a substantial portion of the genus. See *Univ. of Calf. v. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, the courts have indicated what des not constitute same. See, e.g., *In re Gostelli*, 10 USPQ 2d 1614,

1618 (Fed. Cir. 1989), holding that the disclosure of two chemical compounds within a subgenus did not adequately describe such subgenus.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and /or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention form other materials and would lead one f skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

The present disclosure fails to recite a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation of "iodine-based" such that the artisan would readily identify the scope of this active agent. Because there is no support for "iodine-based" in the specification, it is not clear that applicant had possession of the claimed invention at the time of filing.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. *See* Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the values recited by instant claims 1, 2, 8 and 10-11 are incomplete insofar as they do not specify the frame of reference used to measure them, e.g., 0.01% to 20% (claim 1).

In order to overcome this ground of rejection the examiner recommends 0.01% to 20% based on the weight of the composition.

Based on the above reasoning, the instantly claimed percentage values in claims 1, 2, 8 and 10-11 are indefinite insofar as the total against which they are computed is not provided, e.g., “based on the weight of the composition”.

2) The term "powdery" and “granular” in claim 1 is a relative term which renders the claim indefinite. These terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear to

what degree the preparation has to be powdery or granular in order to satisfy the metes and bounds of this claim.

3) Claim 1 is also indefinite since it is not clear what the phrase "powdery/granular" is intended to recite. It is not clear whether the preparation is either granular or powdery or both.

4) Claim 1 is also indefinite since it is not clear that the phrase “procedure of skin damages” means.

5) Claim 1 also recites the phrase “unless otherwise specifically mentioned.” It is also unclear what this phrase intends in relation to the preparation.

6) It is also unclear in claim 1 whether “of 2 mass %" applies to the polymer itself or its relative proportion within the composition.

7) It is also unclear in claim 2 whether “content” refers to the "mass %" of claim 1 in relation to the polymer of its relative proportion within the composition.

8) Claim 9 recites the phrase “iodine-based.” This phrase is indefinite since the relationship between the iodine and the bactericidal agent is unclear.

9) Claim 13 contains the trademark/trade name "macrogol". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polyethylene glycol and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-7 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Shirai et al., (US 4,771,105).

Shirai et al. teach a water absorbent resin of polyacrylic acid series in combination with an aluminum crosslinking compound. (See abstract.) They teach a composition of 100 parts of sodium polyacrylate mixed with 25 parts of aluminum

isopropoxide, for example. (See col. 8, lines 33-45 and Table I.) The composition was dried to about 7% water content. (See ibid.) They teach that the water absorbent resins of their invention may be combined with admixtures such as fluidity assisting agents including bactericide, and used in a similar matter to prior water-absorbent resins. (See col. 6, lines 46-55.) They teach further adding polyethylene glycol (peg). (See col. 3, lines 56-68, col. 4, lines 1-28; see also Example I and Table II at col. 9.)

The reference anticipates the instant claims insofar as it teaches a powder form of sodium polyacrylate, as per claims 1, 3, 4,and 6, where the polymer is more than 5%, as per claims 1-2, and where the crosslinking agent is 20%, a polyvalent metal salt, and contains aluminum, as per claims 1, 5 and 7. The reference also anticipates adding a fluidization agent, as per claims 12-13, where they teach adding polyethylene glycol, which is also macrogol.

The sodium polyacrylate is in an uncross-linked state, as per claim 1, insofar as the crosslinked surface of the resin is formed in the presence of polyhydric alcohol and water. (See col. 2, lines 55-63.)

2) Claims 1-5, 7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (US 4,954,562).

Anderson teaches a water-absorbent resin comprising potassium polyacrylate and titanium dioxide (crosslinking agent), where the water content is 1%. (See Example 1, col. 16, lines 32-36.) The composition contains 48.01% acrylic acid and 2% titanium dioxide. (See table at col. 16.) Example 4, made in the same manner as Example 1,

differs in that it adds 57.95% acrylic acid an aluminum oxide as the crosslinking agent. (See col. 16, lines 56-67, and table at col. 17.) The polymer is in uncross-linked state insofar as the composition has not been exposed to water.

The reverence anticipates the instant claims insofar as it teaches a powdery preparation of 2% or 5% or more of a water-soluble polymer, combined with a crosslinking agent from 0.01% to 20%, as per claims 1 and 2. The polymer has an acid group, and a carboxylic group, as per claims 3 and 4. The crosslinking agent is a polyvalent metal salt, and contains aluminum, as per claims 5 and 7. The moisture content of the preparation is less than 3% as per claim 11.

3) Claims 1-4, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al., (US 5,362,497).

Yamada et al. teaches a transdermal therapeutic composition comprising a super water-absorbent resin. (See abstract) They teach the composition in the form of a hard ointment, where the hard ointment includes macrogols. (See col. 6, lines 25-30; see also claim 9 at col. 12.) The water-absorbent resin used in Example I is Sumikagel SP-510 by Sumitomo Chemical Co., Ltd., which is based on US Patent 4,124,748. (See Example 1 at col. 7, lines 30-33.) It would contain about 25 mole % of acrylic acid and 0.01 mole % of a crosslinking agent.[1] The polymer is in uncross-linked state insofar as the composition has not been exposed to water.

[1] See US Patent 4,124,748 at col. 5, lines 60-65.

The reverence anticipates the instant claims insofar as it teaches a powdery preparation of 2% or more of a water-soluble polymer, combined with a crosslinking agent from 0.01% to 20%, as per claims 1 and 2. The resin is taught to be incorporated into an ointment containing macrogol, as per claims 12 and 13.

4) Claims 1-4 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Makita et al., (US 4,647,636).

Makita et al. teach a process for preparing a highly absorbent resin polymer where the resin contains an alkali metal salt of acrylic or methacrylic at a concentration of about 35%. (See abstract and claim 11 at col. 14.) They teach adding a crosslinking agent in the amount of 0.3% based on the alkali metal salt of acrylic acid or methacrylic acid. (See col. 7, lines 8-14.) They teach further adding a sugar such a saccarose fatty acid as a dispersing agent at a concentration of 10%. (See col. 5, lines 3-17 and lines 29-31.) The polymer is in uncross-linked state insofar as the composition has not been exposed to water.

The reverence anticipates the instant claims insofar as it teaches a powdery preparation of 2% or 5% or more of a water-soluble polymer, combined with a crosslinking agent from 0.01% to 20%, as per claims 1 and 2. The polymer has an acid group, and a carboxylic group, as per claims 3 and 4. The resin further comprises sugars from 5% to 70%, as per claim 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirai (*supra*) as applied to claims 1-7 and 12-13 above, and further in view of Burks, (Physical Therapy 1998).

Shirai, taught above, differs from the instant claims insofar as it does not specify the amount of batericidal agent nor does it teach that the bactericidal agent is iodine based.

Burks teach the use of bactericidal agent povidone-iodine to combat wound infections. (See pg. 212, 1st paragraph.) They teach that povidone-iodine is a commonly used antimicrobial agent. (See id.) They also teach that povidone-iodine is

more effective when used at a concentration of 0.1% to 5%. (See Summary and Clinical Considerations at pg. 216, 2nd paragraph.) They also teach that povidone-iodine is a relatively safe treatment for small acute wounds. (See id. at pg. 217, last paragraph.)

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to provide a bactericidal agent such as povidone-iodine to the composition of Shirai, where the bactericidal agent is at 0.1%, since povidone-iodine is taught be effective at this concentration. The artisan would be motivated to use povidone-iodine since it is commonly used and relatively safe.

2) Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirai (*supra*) as applied to claims 1-7 and 12-13 above, and further in view of Makita et al., (*supra*).

Shirai, taught above, differs from the instant claim 10 insofar as it does not teach further adding sugars of from 5% to 70%.

Makita et al. teach a process for preparing a highly water-absorbent resin and further adding a dispersing agent. (See abstract.) They teach use of a dispersing agent such as saccharose fatty acid esters since they give the desired degree of water-absorbing rate and gel strength to water-absorbent resins. (See col. 5, lines 3-17.) They teach that the amount of dispersing agent is preferably in the range of about 0.001% to about 10%. (See col. 5, lines 29-31.) Makita et al. does not teach sodium polyacrylate or an aluminum-containing crosslinking agent.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to further add sugars at 5%, for example, to the composition of Shirai motivated by their usefulness as dispersing agents that give the desired degree of water-absorbing rate and gel strength to water-absorbent resins.

3) Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirai (*supra*) as applied to claims 1-7 and 12-13 above, and further in view of Anderson (*supra*).

Shirai, taught above, differs from the instant claims in so far as does not teach where the moisture content of the preparation is 3% or less.

Anderson teaches drying their resin to an acceptable water content of a least less than 15% by weight of the polymer. (See col. 3, lines 55-57.) In their examples, the water content was 1%. (See Example 1, col. 16, lines 32-36.)

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to dry the resin of Shirai to 3% or less in view of Anderson. The artisan would reasonably expect success in drying the resin of Shirai to 3% or less, given that Anderson teaches that an acceptable dryness of less that 15% water content and gives an example of 1% water content.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612